

DUPLICATE PAPER

PATENT
Attorney Docket No. 011683-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Robert L. HESS

Serial No.: 07/755,480

Filed: September 5, 1991

For: METHOD AND APPARATUS FOR
RESTENOSIS TREATMENT

Group Art Unit: 3305

Examiner: J. Lacyk

DECLARATION UNDER 37 CFR §1.131

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Robert L. Hess, declare that:

1. I am the inventor of the subject matter claimed in U.S. Patent
Application Serial No. 07/755,480.

2. Exhibit A attached hereto discloses a method for treatment and post-treatment of the stenosed region of an artery. The method includes steps of reducing the annular stenosed area within an artery and advancing a radioactive dose means within the artery to the area of reduced stenosis. The radioactive dose means is operatively connected to positioning means and the advancing step is performed by moving the positioning means. The method also includes steps of applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means and removing the dose means from the artery by moving the positioning means. Exhibit A also discloses apparatus for post-treatment of a stenosed region of an artery that has been reduced by angioplasty or other means. The apparatus includes radioactive dose

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means and positioning means operatively connected to the dose means for advancing the dose means and positioning the dose means within the stenosed region of an artery that has been reduced by angioplasty or other means. The positioning means is also operatively connected to the dose means for withdrawing the dose means from the artery. Exhibit A was prepared in the United States prior to December 11, 1989.

3. Work performed by me or under my direction relating to guide wires and catheters for use with radioactive dose means to be used for treatment and post-treatment of the stenosed region of an artery has been ongoing in the United States from prior to December 11, 1989 through the September 5, 1991 filing date of U.S. Patent Application Serial No. 07/755,480.

The undersigned inventor declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

6 Dec 1992
Date

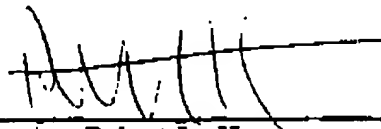

Robert L. Hess

EXHIBIT A

INTERFERON, HOT BALLOONS (LASER: OTHERS) AND THE USE OF STENTS HAVE BEEN THOUGHT TO POTENTIALLY HAVE SOME VALUE IN REDUCING RESTENOSIS RATES. HOWEVER, THE DATA WHICH IS NOW COMING IN SEEMS TO INDICATE THAT THESE METHODS DO NOT SIGNIFICANTLY REDUCE RESTENOSIS RATES. IN RESTENOSIS A PROLIFERATION OF CELLS FOLLOWING ANGIOPLASTY OR ATHERECTOMY CAUSES THE LESION TO REFORM - THE RATE OF RESTENOSIS IN CORONARIES IS CONSIDERED TO BE ABOUT 33%. THEREFORE IT WOULD BE DESIRABLE TO HAVE A MEANS AND A METHOD TO TREAT LESIONS WITH A REDUCED RESTENOSIS RATE - I PROPOSE A CATHETER WHICH HAS, AT ITS DISTAL END, A RADIO ACTIVE SOURCE. THE SOURCE WOULD BE MANEUVERED TO THE SITE OF A LESION WHICH HAS BEEN DILATED OR REMOVED AND THE SITE WOULD BE EXPOSED TO A RADIATION DOSE THAT WOULD KILL SMOOTH MUSCLE CELLS. IF THIS CAN BE DONE IN A CONTROLLED MANNER, IT IS POSSIBLE THAT THE RAPID GROWTH OF CELLS COULD BE PREVENTED AND RESTENOSIS CONTROLLED.

